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Our Ref: MARGMA 40/10/10 *Date:* 20 October 2000

Your Ref:

Docket Management Branch (HFA - 305)
FOOD & DRUG ADMINISTRATION
5630 Fishers Lane, Room 1061
Rockville, MD 20852
U.S.A.

Docket No. 00D-1384

Dear Sirs,

Guidance for Industry:
SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF SURGENONS' AND/OR PATIENT EXAMINATION GLOVES (Recidivist Policy)

1. INTRODUCTION

1.1 We thank the FDA for the opportunity to submit our views and concerns re the above Guidance/Recidivist Policy, on behalf of the glove manufacturing industry in Malaysia.

1.2 The Malaysian Rubber Glove Manufacturers' Association (MARGMA) represents 65 glove manufacturing companies in active production. This works out to be about 80% of the glove manufacturing companies and 80% of the total gloves produced, in Malaysia.

1.3 Our Member Companies have been invited to submit their views and comments. We hereby submit the consolidated views and concerns after the due process of deliberation and consultation.

2. GENERAL VIEW

2.1 MARGMA is appreciative and supportive of the need to uphold the quality of medical gloves, especially of barrier properties, to ensure safety and health to the users at large.

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2.2 Malaysian manufacturers have been producing, and exporting high quality medical gloves all over the world, including the very important U.S. market. We are responsible and business-like manufacturers, and we endeavour to maintain and upgrade our product quality and to meet regulatory requirements.

2.3 ***However, the Guidance/Recidivist Policy under review should be seen and accepted as fair, realistic and pragmatic, though stringent yet reasonable. It should not be punitive in nature but corrective in practice, allowing the manufacturers/shippers the opportunity to rectify their problems immediately, especially at the early stages of violation.*** In a high-volume manufacturing environment, occasional lapses do occur. The sensible recourse is prompt remedial action upon detection/notification.

3. COMMENTS/RECOMMEDATIONS

3.1 Status Quo on Detention Level Until Petition

(a) Hypothetical Case : A batch of production, say extra-small sized patient examination gloves, is put into a few shipments that go out on tight schedule. If found violative and placed on Level 1 Detention, the manufacturer/shipper would soon land himself on Level 2 Detention and/or Level 3 Detention, all within a short period of time, and all because of one unfortunate defective batch.

(b) We propose that the manufacturer/shipper in default remain in the same level of detention for the time being (while on Level 1 Detention or Level 2 Detention), and failures, if any, during that period (when all his shipments are tested by FDA or private labs) be not taken into account as another system failure, until he petitions for removal from detention. However, once the manufacturer/shipper is confident enough to petition for removal from detention, then he is liable for his system control and normal procedure is to be applied.

(c) Rationale :

(i) The American consumers are fully protected during the period of detention as 100% of the shipments in question are tested by FDA or private labs before release/entry into U.S. market.

(ii) All quality systems do allow for failures/defects, and time for corrective and preventive action. Before the manufacturer petitions for release from detention, he uses his time to audit his system and takes corrective action. It would not be fair to move him to the next level of detention for failures which may come from the same batch of production.

(iii) A manufacturer may have supplied good products for the last ten years. It is not fair and too drastic an action to land him in Level 3 Detention for a failure that may have been the result of one violative batch.

3.2 Grounds of Action — Leaks/Pinholes

(a) Guidance :

(i) " ..... detention due to leaks and defects in their gloves." ***(Background)***

(ii) " ..... contain defects/holes, ..." ***(Legal Charges for Defective Gloves)***

(iii) "Because of the presence of defects/holes ....." ***(Guidance to FDA Field Offices)***

(b) FDA emphasizes "***barrier properties***" (glove as a protective barrier) and regards defects to be ***holes***. That is, defect or adulteration is due to pinholes. This is also stated in the Policy [Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects --- Criteria for Direct Reference Seizure (CPG 7124.31)] :

"Surgeons' gloves and patient examination gloves that contain ***holes are adulterated devices.***" (Surgeons' gloves, AQL 2.5; Patient Examination gloves, AQL 4.0).

(d) It is clearly evident that leakage/pinhole defects are actionable. We submit that other ***cosmetic defects*** should not be taken into consideration. That Policy guideline should be appropriately adhered to by the enforcement. Or else, manufacturers who pass the pinhole inspection may be placed on detention for non-critical violation.

3.3 "Sample" Defined

(a) Guidance :

(i) ".....only one (1) defective sample is needed to recommend detention ....." ***(Guidance to FDA Field Offices)***

(ii) " When an entry consists of only one size, attempt to collect as many lot numbers as possible. For example, if during a random sample collection three lot numbers are observed, the sample should represent all of the lots as sub-samples within one sample. If the sample is found violative, all lots should be detained." ***(Sampling)***

(b) There appears to be a confusion over the interpretation of the phrase "*only one (1) defective sample*". We submit that it is meant to be ***one lot number, and not one single piece of glove***, which is highly dangerous and arbitrary.

(c) We therefore propose that the wordings relating to "*only one (1) defective sample*", in the section "Guidance to FDA Field Offices", and all other instructions, be reworded to reflect the real meaning and intention.

3.4 Speedy Communications for Prompt Remedial Action

❶ Feedback from our manufacturers on detention indicates that very often they only come to know of their predicament through 3rd party or website and it will be too late. Meanwhile, subsequent shipments are already on waters or arriving in U.S. ports.

❷ We propose that FDA secure a database of fax numbers and e-mail addresses of all 510 (k)] registrants and circulate it to the field offices, so that manufacturers in default be notified immediately of their violations. This will greatly help both parties (FDA and manufacturers) in resolving the matters at hand.

4. OBSERVATIONS

4.1 Closure of Files After Removal From Detention

(a) Guidance : To be removed from

(i) *Level 1 Detention*
" .... five consecutive medical glove shipments are non-violative ....."
"Good Behaviour/Observation" Period ---24 months

(iii) *Level 2 Detention*
"Evidence documenting 10 consecutive non-violative shipments, ..."
"Good Behaviour/Observation" Period -- 24 months

(b) We propose that the files of manufacturers/shippers who have been removed from Level 1 and Level 2 Detention and after the "Good Behaviour/Observation" Period of 24 months, be removed from the system. Or else, it might unwittingly (i.e. through system error) land them in Level 2 Detention (from level 1) or Level 3 Detention (from Level

2), though they have been duly cleared. In fact, subsequent violation should be treated as a first violation and the procedure is to be applied from the start.

4.2 Timeline for Removal from Detention List

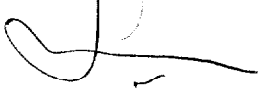
(a) We propose that an early timeline be fixed for removing the manufacturers/shippers from the Detention list, after they have submitted acceptable evidence of non-violative shipments as required. This will help them to cut down expenses and stay focussed on producing better quality gloves.

5. CONCLUSION

5.1 ***MARGMA submits that the manufacturing concern and operational difficulties of the manufacturers be taken into due consideration in modifying the Guidance. The Guidance should be regarded a cooperative and mutually beneficial instrument to ensure acceptable glove quality in the U.S. market. It should be transparently, fairly and objectively administered.***

Thank you very much.

Yours faithfully,
Malaysian Rubber Glove Manufacturers' Association



Andrew Tan
Executive Director

[fda.detention.comment]

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